

EXHIBIT 17

TENNESSEE LETHAL INJECTION PROTOCOL INVESTIGATION

REPORT AND FINDINGS

*Confidential Attorney-Client Communication
And Attorney Work Product*

DECEMBER 13, 2022

INVESTIGATIVE REPORT

***Confidential Attorney-Client Communication
And Attorney Work Product***

To: Governor Bill Lee

From: Butler Snow LLP

Date: December 13, 2022

Subject: Tennessee Lethal Injection Protocol Investigation – Report
and Findings

Preamble

On or about May 2, 2022, Governor Bill Lee (“Governor Lee”) announced plans to conduct a third-party review into the circumstances that led him to issue a reprieve in connection with the April 21, 2022, scheduled execution of Oscar Franklin Smith (“Mr. Smith”). Subsequently, Butler Snow LLP (“Butler Snow”), led by Edward L. Stanton III, was retained to conduct an independent investigation.¹ Specifically, Governor Lee asked Butler Snow to conduct an independent review of the following:

- Circumstances that led to testing the lethal injection chemicals for only potency and sterility but not endotoxins [in connection with] preparing for the April 21 execution;
- Clarity of the lethal injection process manual that was last updated in 2018, and adherence to testing policies since the update; and
- TDOC staffing considerations.²

This report contains an analysis of Butler Snow’s review into the foregoing areas outlined by Governor Lee. While some interviewees expressed opinions regarding the propriety of the death penalty or necessity of endotoxin testing in future protocols, Butler Snow was not asked to examine these issues and did not do so.

Throughout Butler Snow’s investigation, the State of Tennessee has demonstrated an unwavering commitment to transparency and accuracy. The Tennessee Department of Correction (“TDOC”) and the Office of the Tennessee Attorney General (the “Tennessee Attorney General’s Office”) consistently provided the investigative team with the information/documents they sought and gave them prompt access to all relevant employees requested to be interviewed in connection with the instant investigation.

¹ In addition to Edward L. Stanton III, the investigative team included S. Keenan Carter, Jennifer Svilar, and Alexa Ortiz Hadley.

² See Exhibit 1, Governor Lee’s May 2, 2022 Press Release.

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ADDITIONAL DOCUMENTS PROVIDED/REVIEWED

See Appendix.

WITNESS INTERVIEW LIST**Tennessee Attorney General's Office**

- 1 Herbert Slatery — Former Attorney General
- 2 Andrée Blumstein — Solicitor General
- 3 Rob Mitchell — Senior Assistant Attorney General
- 4 Scott Sutherland — Deputy Attorney General
- 5 Dianna Shew — Chief Deputy Attorney General

Tennessee Department of Corrections

- 6 Lisa Helton — Interim Commissioner
- 7 Debbie Inglis — Deputy Commissioner/General Counsel
- 8 Tony Mays — Riverbend Maximum Security Institution Warden
- 9 Kelly Young — Inspector General
- 10 Executioner
- 11 Drug Procurer
- 12 Richard Muckle — Special Assistant to the Commissioner
- 13 Tony Parker — Former Commissioner

Pharmacy

- 14 Former Pharmacy Owner
- 15 Pharmacist
- 16 Current Pharmacy Owner

Reprieve Organization

- 17 Maya Foa — Joint Executive Director
- 18 Blaire Andres — Head of death penalty projects (United States)

Federal Community Defender Office for the Eastern District of Pennsylvania

- 19 Alex Kursman — Assistant Federal Defender (Capital Habeas Corpus Unit)
- 20 Hayden Nelson-Major — Research/Writing Attorney (Capital Habeas Corpus Unit)

Federal Public Defender for the Middle District of Tennessee

- 21 Kelley Henry — Supervisory Assistant Federal Public Defender
- 22 Ben Leonard — Investigator

Bass, Berry & Sims PLC

- 23 David Esquivel
- 24 Jeremy Gunn
- 25 Sarah Miller

Brooklyn Law School

- 26 Alexis J. Hoag-Fordjour — Assistant Professor & Co-Director of the Center for Criminal Justice

EXECUTIVE SUMMARY

As independent investigators, Butler Snow conducted an impartial and comprehensive review of all relevant evidence concerning the three areas referenced in Governor Lee's May 2, 2022, press release. This report addresses all relevant policies/protocols, describes related investigative findings, and recommends specific steps to remedy and/or mitigate the likelihood of any issues recurring in the future. The investigative findings are premised on the following: witness interviews; in-depth historical research; an extensive and thorough review of thousands of pages of relevant documents; and an analysis of lethal injection chemical testing data.

Based on the evidence obtained in the investigation, Butler Snow made the following findings:

A. Circumstances that led to testing the lethal injection chemicals for only potency and sterility but not endotoxins [in connection with] preparing for the April 21 execution

- There is no evidence that any failure to test the lethal injection chemicals for endotoxins in connection with Mr. Smith's scheduled execution on April 21 was intentional.
- There is no evidence that, when the State of Tennessee revised its lethal injection protocol in 2018, it ever provided the pharmacy tasked with testing Tennessee's lethal injection chemicals with a copy of Tennessee's lethal injection protocol.
- There is no evidence that, when the State of Tennessee revised its lethal injection protocol in 2018, any employee ever informed the pharmacy tasked with testing Tennessee's lethal injection chemicals that it should conduct an endotoxin test on all lethal injection chemicals – until the eve of Mr. Smith's scheduled execution on April 21.
- The evidence shows that the pharmacy tasked with testing Tennessee's lethal injection chemicals only tested these chemicals for *potency and sterility*, because the pharmacy followed the United States Pharmacopeia testing guidelines, not Tennessee's lethal injection protocol (which was never provided).

B. Clarity of the lethal injection process manual that was last updated in 2018, and adherence to testing policies since the update

- The evidence shows that the lethal injection chemicals used in the August 9, 2018, execution of Mr. Billy Ray Irick ("Mr. Irick") were not tested for endotoxins. The evidence

further shows that the Midazolam used during Mr. Irick's execution was not tested for potency.

- The evidence shows that, although Edmund Zagorski ("Mr. Zagorski") was executed via electrocution on November 1, 2018, the lethal injection chemicals prepared in the event Mr. Zagorski changed his mind and opted to be executed by lethal injection were not tested in accordance with Tennessee's lethal injection protocol. The lethal injection chemicals were not tested for endotoxins and failed the potency testing.
- The evidence shows that, although David Earl Miller ("Mr. Miller") was executed via electrocution on December 6, 2018, the lethal injection chemicals prepared in the event Mr. Miller changed his mind and opted to be executed by lethal injection were not tested in accordance with Tennessee's lethal injection protocol. The lethal injection chemicals were not tested for endotoxins.
- The evidence shows that the lethal injection chemicals used in the May 16, 2019, execution of Mr. Donnie Edward Johnson ("Mr. Johnson") were not tested for endotoxins.
- The evidence shows that, although Stephen West ("Mr. West") was executed via electrocution on August 15, 2019, the lethal injection chemicals prepared in the event Mr. West changed his mind and opted to be executed by lethal injection were not tested in accordance with Tennessee's lethal injection protocol. The lethal injection chemicals were not tested for endotoxins.
- The evidence shows that, although Lee Hall ("Mr. Hall") was executed via electrocution on December 5, 2019, the lethal injection chemicals prepared in the event Mr. Hall changed his mind and opted to be executed by lethal injection were not tested in accordance with Tennessee's lethal injection protocol. The lethal injection chemicals were not tested for endotoxins.
- The evidence shows that, although Nicholas Sutton ("Mr. Sutton") was executed via electrocution on February 20, 2020, the lethal injection chemicals prepared in the event Mr. Sutton changed his mind and opted to be executed by lethal injection were not tested in accordance with Tennessee's lethal injection protocol. The lethal injection chemicals were not tested for endotoxins.

C. TDOC staffing considerations

- The evidence shows that TDOC leadership placed an inordinate amount of responsibility on the Drug Procurer without providing much, if any, professional guidance; resources; or assistance. Instead, TDOC leadership viewed the lethal injection process through a tunnel-vision, result-oriented lens rather than provide TDOC with the necessary guidance and counsel needed to ensure that Tennessee's lethal injection protocol was thorough, consistent, and followed.

I. METHODOLOGY AND SCOPE OF INDEPENDENT INVESTIGATION

Butler Snow's review of the issues referenced in Governor Lee's May 2, 2022, press release involved the following steps:

- (1) Coordinating with the Tennessee Attorney General's Office to obtain relevant documents and interviewing various attorneys with pertinent information.
- (2) Coordinating with TDOC to obtain relevant documents and interviewing various members of the department with pertinent information.
- (3) Coordinating with the Pharmacy used to supply Tennessee's lethal injection chemicals to obtain relevant documents and interviewing Pharmacy personnel with relevant knowledge.
- (4) Collecting, organizing, reviewing, and analyzing relevant documents and data obtained from the Tennessee Attorney General's Office, TDOC, and the Pharmacy.
- (5) Conducting in excess of 25 interviews including, but not limited to, members of the Tennessee Attorney General's Office, TDOC, and the Pharmacy.

This report is organized in the following sections:

- Section II provides background history and information relating to the events that triggered the instant investigation, the adoption of Tennessee's lethal injection protocol, and TDOC's execution training.
- Section III provides an analysis of the three investigative areas: (1) circumstances surrounding the scheduled execution of Mr. Smith, (2) clarity of and adherence to the lethal injection protocol's testing policy since it was finalized in July 2018, and (3) TDOC staffing considerations.
- Section IV provides a summary of investigative findings and recommendations to address/correct the Tennessee lethal injection protocol shortcomings discussed herein.

II. RELEVANT FACTS AND BACKGROUND

This Section provides an overview of the facts surrounding Governor Lee's granting of a temporary reprieve to Mr. Smith.³ Additionally, this Section provides information on Tennessee's efforts to revise its Lethal Injection Protocols (hereinafter, the "Protocol") and to conduct

³ At age 40, Mr. Smith was convicted of murder in the October 1, 1989, killings of his estranged wife, Judy Robin Smith and her minor sons, Chad Burnett and Jason Burnett.

execution training at TDOC. This Section is intended for background purposes, and additional facts and analysis will follow in the subsequent portions of this Report.

A. Events Triggering Independent Investigation

On April 21, 2022, Mr. Smith was scheduled to be executed by lethal injection. The day before the execution, Mr. Smith's attorneys contacted TDOC's Deputy Commissioner of Administration and General Counsel, Debbie Inglis ("Ms. Inglis" or "Deputy Commissioner/General Counsel"), to confirm whether the lethal injection chemicals ("LIC") that would be used during Mr. Smith's execution had been properly tested in accordance with TDOC's LIC Protocol. TDOC determined that the LIC had not been tested for endotoxins⁴ as required by Tennessee's Lethal Injection Protocol (as revised, July 2018) ("July 2018 Protocol" or "current Protocol"). As a result, Governor Lee issued a temporary reprieve to Mr. Smith on April 21, and on May 2, Governor Lee called for an independent investigation, to be led by Edward L. Stanton, III of Butler Snow. Governor Lee outlined three areas of review:

1. Circumstances that led to testing the LIC for only potency and sterility but not endotoxins preparing for the April 21 execution;
2. Clarity of the lethal injection process manual (the Protocol) that was last updated in 2018, and adherence to testing policies since the update; and
3. TDOC staffing considerations.

B. Adoption of Tennessee's Lethal Injection Protocol

Over the years, the Protocol has been revised multiple times. These revisions include, but are not limited to, title changes, drug changes, format changes, testing requirements, and the addition of consciousness checks. This Section covers the changes pertaining to the LIC used for executions.

⁴ Bacterial endotoxin testing measures the presence and quantity of endotoxins in a particular sample. The "endo" in endotoxins refers to something that is within. The "toxin" component relates to something poisonous. Endotoxins come from the cell walls of gram-negative bacteria.

1. One-Drug Protocol and the Search for Pentobarbital

The Drug Procurer is responsible for obtaining the LIC that will be used in an execution by lethal injection.⁵ This position is not defined in any iteration of the Protocol, nor are the responsibilities of the role discussed in the Protocol. Based on instructions from former TDOC Commissioner Tony Parker (“Commissioner Parker”),⁶ TDOC’s Deputy Commissioner/General Counsel selected the current Drug Procurer in the summer of 2016. The same individual has served as Drug Procurer for all LIC executions following the enactment of the current Protocol in July 2018. The current Drug Procurer described it as an “off the books” role, as procuring LIC is not their⁷ sole responsibility with TDOC.⁸

Prior to the Drug Procurer assuming this role, TDOC carried out executions through a one-drug Protocol using a lethal dose of Pentobarbital. In creating this Protocol, TDOC consulted experts who recommended the one-drug Protocol. Accordingly, the Drug Procurer was specifically instructed, by Commissioner Parker, to locate a new source for Pentobarbital, because the compounding pharmacist TDOC previously used could no longer obtain it.

Because TDOC did not have any policies in place for procuring LIC,⁹ the Drug Procurer began conducting Google searches and making cold calls to active pharmaceutical ingredient (“API”) suppliers located in the United States. They were provided with no direction, just the directive to find a Pentobarbital source. In making calls, the Drug Procurer struggled to find a source to supply Pentobarbital, as pharmacies/manufacturers did not have the chemical; did not

⁵ Although the Drug Procurer is an essential role, its position and corresponding duties are noticeably absent from the current Protocol.

⁶ Commissioner Parker retired from his position as TDOC Commissioner effective on or about November 30, 2021.

⁷ With limited exceptions, this Report uses the pronoun “they” for all individuals referred to herein to preserve anonymity.

⁸ Drug Procurement is neither the job title nor primary role of any TDOC employee.

⁹ Another individual served in this role prior to the current appointee, but that individual is no longer employed with TDOC. The two did not exchange information about the responsibilities of the role.

have the quantity requested by TDOC;¹⁰ or did not want to be associated with lethal injection executions.¹¹ TDOC determined that other states were also facing difficulty when trying to locate a source for Pentobarbital. The Drug Procurer contacted at least one state to get information regarding locating a source for Pentobarbital, but that state did not provide any beneficial information.

In late 2016 to early 2017, the Drug Procurer cold-called a compounding pharmacy that was willing to help look for Pentobarbital and agreed to compound the drug if found. This is the same compounding pharmacy that currently supplies TDOC with compounded LIC based on the Pharmacy Services Agreement entered into with TDOC in 2017 (hereinafter, the "Pharmacy").¹² The Drug Procurer's primary point of contact was the Pharmacy's owner.¹³ Before getting involved with TDOC, the Pharmacy's owners and Pharmacist met to ensure that all individuals were willing to provide LIC (once found) to TDOC for use in executions. None of the individuals voiced any concern or indicated that the Pharmacy should not work with TDOC. As a result, the Pharmacy and Pharmacist undertook efforts to become licensed in Tennessee.

Efforts to find Pentobarbital continued even while the Pharmacy was awaiting licensure in Tennessee. The Pharmacy Owner reached out to various suppliers,¹⁴ but Pentobarbital was either only available in a small quantity, for limited purchasing only, or not available. The Pharmacy Owner found a potential source, but that source would have required the Pharmacy to sign an acknowledgment indicating the chemical would not be used for executions. As a result, the

¹⁰ Text messages between Drug Procurer and Pharmacy Owner, attached hereto as Exhibit 2 at 2-3; Emails between Drug Procurer and potential suppliers, dated Apr. 4, 6, 2017 and June 20, 2018, attached hereto as Exhibit 3.

¹¹ See, e.g., Letter from Alvogen, Inc., dated Apr. 20, 2018, attached hereto as Exhibit 4; Letter from Hikma Pharmaceuticals USA Inc., dated Feb. 26, 2020, attached hereto as Exhibit 5; Letters from Sandoz, Inc., dated Aug. 15, 2019 and Aug. 2, 2018, attached hereto as Exhibit 6.

¹² Pharmacy Services Agreement, attached hereto as Exhibit 21.

¹³ The Pharmacy Owner left the Pharmacy in early 2020, and from that point forward, the Drug Procurer communicated with the Pharmacist directly.

¹⁴ Text messages between Drug Procurer and Pharmacy Owner, attached hereto as Exhibit 2 at 3 (listing the following suppliers: Cardinal Health, McKesson, Medisca, PCCA, ANDA, Amerisource Bergen, Sigma Aldrich).

Pharmacy could not use the source. The Pharmacy Owner and Drug Procurer also considered the possibility of obtaining Pentobarbital from a veterinarian because “[t]hey sometimes have better access to it since it’s widely used for euthanasia in animals.”¹⁵ That effort never came to fruition.

It became clear to TDOC that it was extremely difficult finding a U.S.-based source that would provide Pentobarbital in the amount needed for use in lethal injection executions. The Drug Procurer and Pharmacy Owner also investigated whether the drug could be obtained from an international source and imported.¹⁶ It was ultimately determined that the United States Drug Enforcement Administration (“DEA”) would not allow Pentobarbital to be imported because it is a schedule II drug that was considered “readily available” in the United States.¹⁷

Even if considered “readily available” by the DEA, TDOC was unable to obtain Pentobarbital. Because Pentobarbital was unavailable, TDOC made the decision to adopt a three-drug Protocol. The Drug Procurer’s efforts to locate Pentobarbital continued into at least 2020,¹⁸ even after TDOC adopted its new three-drug Protocol and removed the Pentobarbital Protocol (identified as Protocol A) from TDOC’s current Protocol. Even today, TDOC officials prefer a one-drug protocol to the three-drug protocol.¹⁹ With a one-drug protocol, TDOC representatives told investigators there is a lower risk of mistake in carrying out an execution. Further, according to at least one TDOC official, the potential for mistakes also increases when more compounded LIC are used.

2. First Iteration of Three-Drug Protocol (January 2018)

Having been unable to obtain Pentobarbital for its then one-drug Protocol, in the Fall of 2017, TDOC began inquiring about developing a new three-drug Protocol. Commissioner Parker

¹⁵ Text messages between Drug Procurer and Pharmacy Owner, dated Apr. 6, 2017, attached hereto as Exhibit 2 at 1.

¹⁶ Emails between Drug Procurer and Pharmacy Owner, dated May 15, 2019, attached hereto as Exhibit 7; Emails between Drug Procurer and Pharmacy Owner, dated July 20, 2017, attached hereto as Exhibit 8.

¹⁷ Emails between Drug Procurer and Pharmacy Owner, dated Oct. 30, 2019, attached hereto as Exhibit 9.

¹⁸ Handwritten Notes of Drug Procurer, dated Feb. 25, 2020, attached hereto as Exhibit 10.

¹⁹ Dep. Tr. of Debbie Inglis at 37-39, attached hereto as Exhibit 11.

did some research on his own but relied on his Deputy Commissioner/General Counsel, the Drug Procurer, and the Tennessee Attorney General's Office to establish the new, three-drug Protocol. Commissioner Parker reviewed the written Protocol but did not have any involvement in drafting it, including the portions that address testing of LIC, which he assumed were drafted in consultation with the Pharmacist.²⁰

In early September of 2017, the Drug Procurer informed the Pharmacy Owner that TDOC wanted "to try to find Midazolam and then go from there" if Midazolam was unavailable.²¹ The Pharmacy Owner responded that both Midazolam and Potassium Chloride were "readily available" and that they had "reviewed several protocols from states" with three-drug protocols that use those drugs along with a paralytic.²² The Pharmacy Owner voiced "concern with Midazolam," stating that "[b]eing a benzodiazepine, it does not elicit strong analgesic effects," meaning "[t]he subjects may be able to feel pain from the administration of the second and third drugs." The Drug Procurer agreed to "pass this info on to the higher ups."²³

Nevertheless, TDOC chose to proceed with a three-drug Protocol that included Midazolam, Vecuronium Bromide, and Potassium Chloride. The Drug Procurer notified the Pharmacy Owner of this decision on September 21, 2017 and asked various questions about the dosage for each, available quantity, cost, shelf life and storage conditions.²⁴ In response, the Pharmacy Owner explained that the Vecuronium Bromide was available in a powder which would require reconstituting, noted the "typical dosing" for Potassium Chloride, and advised on the quantity required for both.²⁵ The Pharmacy Owner further explained that "there would be no need to

²⁰ Commissioner Parker never spoke to the Pharmacist, as he was advised against such contact by TDOC's attorneys.

²¹ Emails between Drug Procurer and Pharmacy Owner, dated Sept. 7, 2017, attached hereto as Exhibit 12. (RE: Update)

²² *Id.*

²³ *Id.*

²⁴ Emails between Drug Procurer and Pharmacy Owner, dated Sept 21, 2017, attached hereto as Exhibit 13.

²⁵ *Id.*

compound” at that point and that the commercially available drugs could be maintained at room temperature and would have a shelf life of one to two years.²⁶ The Drug Procurer communicated this information back to their TDOC superiors.

The Pharmacy began obtaining commercially-manufactured LIC in October 2017. According to the Pharmacy Owner, by October 18, 2017, the Pharmacy had received Midazolam that would expire in June 2018, Vecuronium Bromide that would expire in December 2018, and Potassium Chloride that would expire in May 2018.²⁷ On October 26, 2017, the Drug Procurer again asked the Pharmacy Owner for information on how the LIC needed to be stored as well as how to prepare them for injection.²⁸ The Pharmacy Owner replied that the LIC should be “stored in a secured location at room temperature (between 15 and 30 degrees [Celsius]),” and that they would instruct the Pharmacist to draft a protocol on how to prepare them.²⁹ The Pharmacy Owner also attached a proposed Pharmacy Services Agreement, which contained terms related to the Pharmacy’s provision of prescription medication and compounded preparations. The Pharmacy Owner and Drug Procurer discussed and made various changes to the terms of this Agreement, but the Pharmacy requirements related to compounding (including compliance with pharmaceutical standards, the United States Pharmacopoeia guidelines and accreditation departments) remained the same.

Around that same time, the Drug Procurer and Pharmacy Owner exchanged a draft of certain pages of the Protocol in development. In particular, the Drug Procurer provided the Pharmacy Owner with copies of six pages of the Protocol, including full sections entitled “Chemicals Used in Lethal Injection” and “Protocol B: Lethal Injection Chemical Set-Up and Preparation,” as well as one page of the section ultimately entitled “Chemical Administration and IV Monitoring.”³⁰ The Pharmacy Owner made one revision to these pages, changing the size of

²⁶ *Id.*

²⁷ Emails between Drug Procurer and Pharmacy Owner, dated Oct. 18, 2017, attached hereto as Exhibit 14.

²⁸ Emails between Drug Procurer and Pharmacy Owner, dated Oct. 26, 2017, attached hereto as Exhibit 15.

²⁹ *Id.*

³⁰ Edited Excerpt of Protocol, attached hereto as Exhibit 16.

the syringe used for administration of Potassium Chloride to reduce the number of syringes used in an execution from three to two. The Pharmacy Owner sent these revisions to the Drug Procurer on November 28, 2017, along with a signed copy of the finalized Pharmacy Services Agreement.³¹

As of December 2017, the Protocol had not yet been updated. In preparation for the transition to the new three-drug Protocol, by the end of 2017, TDOC had acquired a bulk order of commercially manufactured Midazolam, Vecuronium Bromide, and Potassium Chloride from the Pharmacy. This order kickstarted the first revision of the Protocol to add the three-drug protocol. The January 2018 version of the Protocol included both protocol alternatives using commercially-manufactured drugs: (A) lethal injection by Pentobarbital and (B) lethal injection by Midazolam, Vecuronium Bromide, and Potassium Chloride.

CHEMICALS USED IN LETHAL INJECTION	
The Department will use one of the following protocols as determined by the Commissioner:	
<u>Protocol A:</u>	
Pentobarbital	100 ml of a 50 mg/mL solution (a total of 5 grams)
<u>Protocol B:</u>	
Midazolam	100 ml of a 5mg/ml solution (a total of 500 mg)
Vecuronium Bromide	100 ml of a 1mg/ml solution (a total of 100 mg)
Potassium Chloride	120 ml of a 2 mEq/ml solution (a total of 240 mEq)

Protocol A was kept because TDOC's search for Pentobarbital was ongoing. Because the January 2018 Protocol does not provide for the use of compounded LIC, there is no discussion of testing in this version of the Protocol.

³¹ Emails between Drug Procurer and Pharmacy Owner, dated Nov. 28, 2017 through Dec. 4, 2017, attached hereto as Exhibit 17.

3. Revisions Ahead of July 2018 Protocol

Executions resumed under Tennessee's current Protocol in mid-2018, beginning with the execution of Billy Ray Irick ("Mr. Irick") on August 9, 2018. By this point, TDOC had Potassium Chloride and Vecuronium Bromide that would not expire until July 2019 and June 2020, respectively; however, the Midazolam it had previously acquired was scheduled to expire in June 2018, meaning TDOC would need to procure additional Midazolam for executions.³²

By the time TDOC began efforts to acquire additional Midazolam in 2018, the Pharmacy was no longer able to obtain it in a commercially manufactured form due to suppliers requesting assurances that the drug would not be used for executions. As a result, TDOC began ordering Midazolam in its API form to be compounded by the Pharmacy. Based upon information conveyed to investigators, compounded drugs—in contrast to their commercially manufactured counterparts—should undergo certain testing under pharmaceutical guidelines, have different storage and preparation requirements, and have a much shorter shelf life.

In July 2018, TDOC, in coordination with the Tennessee's Attorney General's Office, revised the initial three-drug Lethal Injection Protocol to include reference to these additional requirements where the LIC are compounded. TDOC also removed alternative "A" – the Pentobarbital protocol – given TDOC's continued inability to obtain it.³³

³² LIC Inventory Page, dated Dec. 30, 2017, attached hereto as Exhibit 18.

³³ Edited Protocol, attached hereto as Exhibit 19.

CHEMICALS USED IN LETHAL INJECTION

The Department will use the following protocol for carrying out executions by lethal injection:

Midazolam	100 ml of a 5mg/ml solution (a total of 500 mg)
Vecuronium Bromide	100 ml of a 1mg/ml solution (a total of 100 mg)
Potassium Chloride	120 ml of a 2 mEq/ml solution (a total of 240 mEq)

Chemicals used in lethal injection executions will either be FDA-approved commercially manufactured drugs; or, shall be compounded preparations prepared in compliance with pharmaceutical standards consistent with the United States Pharmacopeia guidelines and accreditation Departments, and in accordance with applicable licensing regulations.

According to the Drug Procurer, they consulted the Pharmacy Owner in the course of TDOC's revision of the Protocol, particularly with respect to testing and storage requirements and compliance with the United States Pharmacopoeia ("USP") guidelines. The Drug Procurer told investigators that, the Pharmacy Owner recommended testing for sterility,³⁴ potency³⁵ and endotoxins for compounded LIC. Interestingly, both the Pharmacy Owner and Drug Procurer expressed the belief to investigators that sterility testing included endotoxin testing,³⁶ but according to the Pharmacist, there are separate tests for sterility and endotoxins. Further, the Pharmacist noted that USP Chapter 797 only requires testing for endotoxins when compounding more than 25 doses at a time. When compounding single-dose vials—as the Pharmacist does for TDOC—the Pharmacist understands that USP Chapter 797 does not require endotoxin testing and

³⁴ Sterility testing is used to confirm sterile products do not contain viable microorganisms before release and patient administration.

³⁵ Potency testing measures the concentration of the API. It is necessary to ensure the quality, safety, and efficiency of biopharmaceutical products.

³⁶ The Pharmacy Owner, like the Drug Procurer, is not a pharmacist and has had no pharmaceutical training. The Pharmacy Owner's medical training consists of on-the-job training as an orthopedic scrub technician.

only requires “skip lot” testing (i.e. testing approximately every other batch) for sterility and potency. Regardless, there is no dispute that TDOC’s current Protocol requires endotoxin testing.

4. July 2018 Protocol and Extra-Protocol Instructions

The resulting, revised Protocol requires a physician’s order for compounded drugs and requires the Pharmacist to compound the drugs “in a clean sterile environment in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with the United States Pharmacopoeia guidelines and accreditation Departments and in accordance with applicable licensing regulations pertaining to pharmacies compounding sterile preparations.”³⁷ The current Protocol then references the Pharmacy Services Agreement, which contains nearly identical language.³⁸ The current Protocol further requires the Pharmacist to arrange for independent testing of compounded drugs for potency, sterility and endotoxins.³⁹ Finally, it defers to the Pharmacy’s directions, pharmaceutical standards, and the USP guidelines with respect to the transfer, storage and maintenance of compounded LIC,⁴⁰ as well as Pharmacy directions for preparing the syringes for use in an execution.⁴¹

Specific directions related to the preparation of syringes for compounded LIC were not included in the current Protocol itself. Instead, the Pharmacy provided the Drug Procurer with separate preparation instructions for Midazolam—the only compounded LIC in use at the time—in July 2018.⁴² Similarly, because compounded drugs must be transported and stored at below-

³⁷ July 2018 Protocol, attached hereto as Exhibit 20 at 35.

³⁸ *Id.*

³⁹ *Id.* The testing requirements also appeared in a 2015 version of a Pharmacy Services Agreement that TDOC may have had with its previous compounding pharmacy. See Agreement, dated June 25, 2015, attached hereto as Exhibit 21. This language does not appear in the current Agreement between TDOC and the Pharmacy.

⁴⁰ July 2018 Protocol, Exhibit 20 at 35.

⁴¹ *Id.* at 39.

⁴² Email from Pharmacy Owner to Drug Procurer, dated July 16, 2018, including Revised IV Protocol, attached hereto as collective Exhibit 22.

freezing temperatures, the Pharmacy also provided Directions for Unpacking and Storage⁴³ with each shipment of compounded LIC, which were packed with dry ice. The Midazolam Preparation Instructions require transfer of the compounded Midazolam from the freezer to the refrigerator 24 hours prior to use and explain how to prepare the syringe, which includes adding both Midazolam and saline solution to the syringe.⁴⁴ Neither the current Protocol nor these instructions explain how far in advance of an execution compounded LIC should be removed from the refrigerator and prepared in a syringe.⁴⁵

In advance of Mr. Irick's scheduled execution, on or about August 7, 2018,⁴⁶ the Pharmacy Owner and Pharmacist participated in a phone call with the Executioner and at least one intravenous ("IV") Team Member for the purpose of (1) explaining how to prepare the Midazolam, (2) explaining how to reconstitute the Vecuronium Bromide, and (3) answering questions from the Execution Team.

C. Execution Training

In order to carry out safe and effective executions, Riverbend Maximum Security Institution ("RMSI") conducts monthly practice drills.⁴⁷ Under the Protocol, members of the Execution Team simulate Day 3 (day of execution) of the death watch procedures for at least one hour per month.⁴⁸ The training may last longer if needed. Additional training is held within two

⁴³ Directions for Unpacking and Storage, attached hereto as Exhibit 23.

⁴⁴ Revised IV Protocol, Exhibit 22 at 2-4.

⁴⁵ Drug Procurer asked Pharmacy Owner about this via text message on July 5, 2018, to which Pharmacy Owner responded "My assumption is that it would need to be used within an hour. I'll confirm with the pharmacist." Text Message between Drug Procurer and Pharmacy Owner, dated July 5, 2018, attached hereto as Exhibit 24.

⁴⁶ Emails between Pharmacy Owner and Pharmacist, dated Aug. 7, 2018, attached hereto as Exhibit 25; Text messages between Drug Procurer and Pharmacy Owner, dated Aug. 7, 2018, attached hereto as Exhibit 26

⁴⁷ As part of the investigation, Butler Snow's investigative team attended one of the monthly training sessions in person.

⁴⁸ Protocol, Exhibit 20 at 32.

weeks before a scheduled execution, at which point RMSI conducts rehearsals at least twice per week.⁴⁹

As lethal injection is the primary method of execution in Tennessee, the monthly training focuses on the procedures for carrying out executions by lethal injection. Every quarter, RMSI also practices its procedures for carrying out executions by electrocution. If an execution by electrocution is scheduled, then the Execution Team will focus more on those procedures during the monthly training sessions. The Warden oversees all such training, and the TDOC Commissioner also attends many of the practices. All individuals who undergo the training are required to sign training rosters, which are maintained by TDOC.

During the lethal injection training, all steps of an execution are practiced with the following exceptions, as outlined in the Protocol:

- A. [TDOC staff] volunteers play the roles of the condemned inmate and the physician.
- B. Saline solution is substituted for the lethal chemicals.
- C. A body is not placed in the body bag.⁵⁰

Beyond monthly training, the Executioner receives initial and periodic instruction from a qualified medical professional.⁵¹ For instance, the Executioner and other members of the IV Team have received training on how to start an IV in case the emergency medical technicians (“EMTs”) are not available. During training, the IV Team practices pushing three syringes of saline, and because they cannot push the actual LIC, nor can they compound any LIC on hand, they simulate the remaining syringes.

⁴⁹ Protocol, Exhibit 20 at 32.

⁵⁰ Protocol, Exhibit 20 at 32.

⁵¹ Protocol, Exhibit 20 at 32.

III. INVESTIGATIVE ANALYSIS

This section provides Butler Snow's analysis of the facts learned through document review and investigative interviews based on the three areas of investigation provided by Governor Lee.

A. Circumstances Surrounding the Scheduled Execution of Oscar Franklin Smith

Oscar Franklin Smith was originally scheduled to be executed on June 4, 2020.⁵² Mr. Smith filed a motion to stay his execution due to the COVID-19 pandemic, and a stay was granted on April 17, 2020.⁵³ His execution was initially reset for February 4, 2021.⁵⁴ The COVID-19 stay was lifted, and Mr. Smith's execution was reset for April 21, 2022.⁵⁵ On March 21, 2022, TDOC informed Mr. Smith that his execution would be carried out by lethal injection "according to the protocol and procedures in TDOC's Lethal Injection Manual, as amended on July 5, 2018, using a three-drug combination consisting of Midazolam, Vecuronium Bromide, and Potassium Chloride."⁵⁶

A physician's prescription for Midazolam and Potassium Chloride was issued for Mr. Smith on March 16, 2022.⁵⁷ The Pharmacy compounded the Midazolam and Potassium Chloride and sent samples to the independent testing laboratory⁵⁸ (the "Lab") for sterility and potency testing on or about March 18 (Potassium Chloride) and April 6 (Midazolam) of 2022. The Potassium Chloride sample passed sterility testing on March 21, and the Midazolam sample passed

⁵² Order, *Smith v. State of Tennessee*, Case No. M2016-01869-SC-R11-PD, attached hereto as Exhibit 27.

⁵³ Notice – Order – Stay Execution (Death) Granted, *Smith v. State of Tennessee*, Case No. M2016-01869-SC-R11-PD, attached hereto as Exhibit 28.

⁵⁴ *Id.*

⁵⁵ Notice – Order (Other) – Miscellaneous (Sua Sponte), *Smith v. State of Tennessee*, Case No. M2016-01869-SC-R11-PD, attached hereto as Exhibit 29.

⁵⁶ Smith Notification Letter, dated Mar. 21, 2022, attached hereto as Exhibit 30.

⁵⁷ Smith Prescription, dated Mar. 16, 2022, attached hereto as Exhibit 31.

⁵⁸ The Pharmacy has used the same independent testing laboratory since it began working with TDOC.

sterility testing on April 20.⁵⁹ The Potassium Chloride sample yielded a within-range potency of 103% on March 31, and the Midazolam sample yielded a within-range potency of 102% on April 8. The Pharmacist subsequently provided the test results to the Drug Procurer.⁶⁰ The samples were not tested for endotoxins.

The LIC arrived at RMSI on or about April 12. On April 12, 14 and 18, lethal injection training was conducted at the prison.⁶¹ On April 20, the LIC were moved to the refrigerator for thawing prior to the execution. Also, on April 20, Mr. Smith's attorney, Kelley Henry ("Ms. Henry"), sent an email to TDOC's Deputy Commissioner/General Counsel (1) inquiring about whether the LIC to be used in Mr. Smith's execution had been tested for "strength, sterility, stability, potency, and presence of endotoxins" and (2) requesting a copy of the test results.⁶² The Deputy Commissioner/General Counsel informed TDOC Interim Commissioner Lisa Helton ("Interim Commissioner Helton") about Ms. Henry's request.

The Deputy Commissioner/General Counsel forwarded the email to the Drug Procurer⁶³ to determine the status of the LIC testing. The Drug Procurer, in turn, contacted the Pharmacist on April 20 to determine if an endotoxin test had been conducted or if the endotoxin test was the same as sterility testing.⁶⁴ According to a text exchange between the Drug Procurer and the Pharmacist: "No endotoxin test, it's a different test but based on USP 797 the amount we make isn't required.

⁵⁹ Based on this date, the Pharmacist would have had to send the LIC to the Drug Procurer before the test results came back because the execution was scheduled for the following day (April 21), and the LIC must thaw for 24 hours before they can be used. Butler Snow did not find any evidence of when the LIC were sent for Mr. Smith's execution.

⁶⁰ Testing Reports, dated Mar. 21, 31, and Apr. 8, 20, 2022, attached hereto as Exhibit 32.

⁶¹ See *supra* for a discussion of TDOC's execution training protocols.

⁶² Email from K. Henry to D. Inglis, dated April 20, 2022, attached hereto as Exhibit 33. Ms. Henry also sent a follow-up email on April 21, 2022, at 5:50:42 PM, again requesting the testing results. A copy of this email is attached hereto as Exhibit 34. Later that same day, Ms. Henry sent an email asking TDOC to preserve all records, documents, drugs, and drug paraphernalia that were to be used in Mr. Smith's execution. A copy of this email is attached hereto as Exhibit 35.

⁶³ Other individuals with TDOC and the Tennessee Attorney General's office received the email, either by virtue of being cc'd or via forward.

⁶⁴ Text messages between Drug Procurer and Pharmacist, dated Apr. 20-21, 2022, attached hereto as Exhibit 36.

Is the endotoxin test requested? Sorry I didn't have it tested."⁶⁵ The Drug Procurer indicated a belief that endotoxin testing had been done on prior occasions and that they would contact the Pharmacist on the following day to discuss the USP 797 guidelines.⁶⁶ Therefore, at least one TDOC employee was aware that no endotoxin testing had been conducted on the LIC during the evening of the day before Mr. Smith's scheduled execution.

1. Day of Execution: TDOC

On the morning of April 21, 2022, the Drug Procurer asked the Pharmacist whether the Lab still had samples and would be able to do the endotoxin testing that day.⁶⁷ The Pharmacist responded that the testing could not be done because they would have had to send extra samples for the Lab to do endotoxin testing.⁶⁸ Around lunchtime on April 21, TDOC employees who were to be involved in the execution gathered at Interim Commissioner Helton's residence for a final walk-through – which is customary on the scheduled day of an execution. During this time, there were also ongoing conversations between TDOC, the Tennessee Attorney General's Office, and Governor Lee's office. TDOC advised that if the LIC were not tested for endotoxins, then TDOC would need to ask Governor Lee for a reprieve. At that point, the Drug Procurer indicated that the testing was not required by USP guidelines. Even so, it was required by the current Protocol, and as such, TDOC would seek a reprieve because the Protocol was not followed. The Tennessee Attorney General's Office also recommended a reprieve.

During the afternoon of Mr. Smith's execution day, while the reprieve request was still being considered, the Execution Team needed to proceed as though the execution would go as scheduled. For instance, Execution Team members needed to take their stations, and the victims' family needed to be moved to their locations. Media representatives also were scheduled to be at RMSI for the execution. For this reason, Interim Commissioner Helton chose to move forward and

⁶⁵ *Id.*

⁶⁶ *Id.* The Pharmacist also testified in a deposition to having tested for endotoxins before, but as explained above, they only did endotoxin testing on the initial batch of Midazolam when they were testing the methodology.

⁶⁷ *Id.*

⁶⁸ *Id.*

continue preparing for the execution until the reprieve was issued. Around 4:30 PM CT, the Drug Procurer met the Executioner to get the LIC out of the refrigerator and transport the LIC to the Execution Chamber.⁶⁹ About 5:30 PM CT, the Execution Team began preparing the syringes to be used during the execution.

TDOC learned that the reprieve would be issued at 5:45 PM CT. Interim Commissioner Helton advised Warden Tony Mays, who told Mr. Smith about the reprieve. Mr. Smith's attorney and spiritual advisor were also present when the news was delivered. Interim Commissioner Helton also spoke with members of TDOC to assure them that they had done a good job preparing for the execution. Once the execution was called off, TDOC stopped setup of the LIC at approximately 5:51 PM CT.⁷⁰ The Execution Team had partially prepared the first (red) set of LIC (saline and Vecuronium Bromide) but had not yet mixed the compounded LIC. TDOC then undertook efforts to preserve the LIC and all documentation in the event of an investigation.⁷¹

2. Day of Execution: Tennessee's Attorney General's Office

Around 1:30 PM CT on April 21, 2022, members of the Tennessee Attorney General's Office met to review documents, review the Protocol, and discuss next steps. The Tennessee Attorney General's Office team concluded that they could not state that TDOC followed the Protocol in preparing for Mr. Smith's execution. Accordingly, the attorneys turned their focus to how best to respond to Mr. Smith's attorney's inquiry. They also spoke with the Pharmacist, who indicated that they had done endotoxin testing in the past but not for the LIC to be used in Mr. Smith's execution. At this point, the Pharmacist purportedly indicated that the lack of endotoxin testing was an "oversight."⁷² The group also spoke with the Drug Procurer, and one member of the Tennessee Attorney General's Office spoke with an expert, who was also a pharmacist and

⁶⁹ Text messages between Drug Procurer and Executioner, dated Apr. 21, 2022, attached hereto as Exhibit 37.

⁷⁰ Drug Procurer text messages, dated Apr. 20-22, 2022, attached hereto as Exhibit 38.

⁷¹ Inventory of Items Preserved from Apr. 21, 2022 Execution Prep, attached hereto as Exhibit 39.

⁷² The Pharmacist was clear when speaking to Butler Snow that only one endotoxin test had ever been performed because it was not required under the USP guidelines based on the amount of drugs compounded. The purpose of the one endotoxin test, performed in May 2018, was to test the Pharmacy's compounding methodology.

explained why endotoxin testing was important. After the reprieve was issued, members of the Tennessee Attorney General's Office were invited to the executive residence for a meeting with Governor Lee regarding the execution events.

3. Days Following Cancelled Execution

After issuing the reprieve in connection with Mr. Smith's execution, Governor Lee's office asked for a copy of the current Protocol and other documents that would aid in determining why the LIC were not tested for endotoxins. TDOC compiled the requested documents and provided them to Governor Lee's office. At some point between April 21 and 27, the question was raised regarding whether endotoxin testing had been conducted in connection with the lethal injection executions TDOC conducted as scheduled subsequent to adopting the July 2018 Protocol. The Pharmacist apparently had informed the Drug Procurer that they had not done endotoxin testing for any of the prior executions because the test was not required under USP guidelines. The Pharmacist indicated to Butler Snow that they were surprised when the Drug Procurer asked if endotoxin testing had been performed for the LIC for Mr. Smith's execution because they had never been asked to do endotoxin testing before. The Pharmacist was also unaware that endotoxin testing was part of the Protocol. In fact, Butler Snow has found no evidence that the current Protocol was ever provided to the Pharmacy. It appears that the Pharmacist was following the USP guidelines to determine what tests to conduct on the LIC, because TDOC never sent them the Protocol. The Pharmacist had no way of knowing TDOC finalized and implemented the Protocol. The Tennessee Attorney General's Office requested documents, including all LIC testing records. On April 22, 2022, the Tennessee Attorney General's Office received 31 pages of testing results dating back to 2018, although only 17 of those had been produced previously in litigation.

On April 24, in response to an inquiry from the Governor's office, the Drug Procurer provided the following information regarding TDOC's policies for lethal injection: (1) the Protocol does not require any additional testing of the LIC beyond the tests conducted by the Lab after the Pharmacy compounds the LIC; (2) there is no policy or procedure in place to address how the LIC test results are to be maintained following TDOC's receipt; (3) there is no log book to track periodic testing, since it is not required, but all third-party test results are received and maintained

by the Drug Procurer; and (4) there are no documents evidencing TDOC's review (yearly or otherwise) of the Protocol.⁷³

By April 27, it became clear that none of the LIC used and/or prepared for post-2018 executions had been tested for endotoxins. Further, TDOC learned that there were additional problems with the testing of the LIC used in Mr. Irick's execution in 2018 because there was also no potency testing completed.⁷⁴ The explanation provided by the Pharmacy Owner at the time was that the potency test conducted for the batch in May 2018 was good for the LIC provided for the scheduled execution of Mr. Irick in August 2018. Through the course of their post Mr. Smith reprieve dialogue with the Pharmacist, TDOC learned that this was in fact not true.

As stated earlier in this Report, there is no indication that TDOC provided the Pharmacy with a copy of the July 2018 Protocol, under which all of the executions covered in this Report were carried out. The Pharmacist did not conduct endotoxin testing unless it was requested, and TDOC did not specifically request endotoxin testing results until the day of Mr. Smith's execution. However, TDOC consistently only requested sterility and potency testing results from the Pharmacy in connection with each scheduled lethal injection execution.⁷⁵

B. Adherence to Protocol's Testing Policies Since Update in July 2018

Since the Protocol was updated in July 2018, there have been a total of seven executions, two of which were by lethal injection, and five of which were by electrocution.⁷⁶ Butler Snow's review of TDOC's adherence to the Protocol necessitated a review of each execution carried out by TDOC since adoption of the July 2018 Protocol. Butler Snow discovered that only one sample of Midazolam was ever tested for endotoxins, and no samples of Potassium Chloride were tested

⁷³ Emails between Gov. Lee's office and TDOC, dated Apr. 21-24, 2022, attached hereto as Exhibit 40.

⁷⁴ See *infra* for more information.

⁷⁵ TDOC likely did not request endotoxin testing because the Drug Procurer was operating under the mistaken belief that endotoxin testing was incorporated in the sterility testing.

⁷⁶ Executions by electrocution are covered under TDOC's Electrocution Protocol (updated March 13, 2017). These executions are only discussed here because, as explained above, TDOC decided to have LIC available for all executions, regardless of the method chosen by the condemned.

for endotoxins. The only endotoxin test was conducted in May 2018, a few months before Mr. Irick's execution. The following is an illustration of the LIC testing results during the relevant timeframe:

LIC Testing Results Spreadsheet

Test Date	Drug	Test	Results	Date Received	Inmate
5/22/2018	Midazolam	Suitability	Pass	5/10/2018	Irick
5/14/2018	Midazolam	Container Closure Integrity	Pass	5/10/2018	Irick
5/11/2018	Midazolam	Potency	97.00%	5/10/2018	Irick
5/11/2018	Midazolam	Bacterial Endotoxins	Pass	5/10/2018	Irick
5/25/2018	Midazolam	Sterility	Pass	5/10/2018	Irick
8/6/2018	Midazolam	Sterility	Pass	7/21/2018	Irick
9/24/2018	Midazolam	Potency	94.20%	9/22/2018	Zagorski
10/8/2018	Midazolam	Sterility	Pass	9/22/2018	Zagorski
11/7/2018	Midazolam	Potency	54.20%	10/27/2018	Zagorski
12/4/2018	Midazolam	Potency	89.40%	11/21/2018	Miller
12/5/2018	Midazolam	Sterility	Pass	11/21/2018	Miller
4/26/2019	Midazolam	Potency	104.00%	4/25/2019	Johnson
5/9/2019	Midazolam	Sterility	Pass	4/25/2019	Johnson
7/17/2019	Potassium Chloride	Potency	112.00%	7/16/2019	West
7/30/2019	Potassium Chloride	Sterility	Pass	7/16/2019	West
7/18/2019	Midazolam	Potency	92.40%	7/16/2019	West
7/30/2019	Midazolam	Sterility	Pass	7/16/2019	West
7/31/2019	Potassium Chloride	Suitability	Pass	7/26/2019	West
8/12/2019	Potassium Chloride	Potency	94.00%	8/6/2019	West
8/7/2019	Potassium Chloride	Potency	94.00%	8/6/2019	West
8/9/2019	Potassium Chloride	Sterility	Pass	8/6/2019	West
11/18/2019	Midazolam	Potency	114.00%	11/13/2019	Hall
11/22/2019	Midazolam	Potency	98.60%	11/21/2019	Hall
12/5/2019	Potassium Chloride	Potency	94.70%	12/2/2019	Hall
12/5/2019	Midazolam	Sterility	Pass	11/21/2019	Hall
12/16/2019	Potassium Chloride	Sterility	Pass	12/2/2019	Hall
1/17/2020	Potassium Chloride	Potency	104.00%	1/14/2020	Sutton
1/28/2020	Potassium Chloride	Sterility	Pass	1/14/2020	Sutton
1/27/2020	Midazolam	Potency	100.00%	1/14/2020	Sutton
1/28/2020	Midazolam	Sterility	Pass	1/14/2020	Sutton
7/21/2020	Potassium Chloride	Potency	99.50%	7/17/2020	Nichols

Test Date	Drug	Test	Results	Date Received	Inmate
7/21/2020	Midazolam	Potency	98.40%	7/17/2020	Nichols
7/31/2020	Midazolam	Sterility	Pass	7/17/2020	Nichols
7/31/2020	Potassium Chloride	Sterility	Pass	7/17/2020	Nichols
4/8/2022	Midazolam	Potency	102.00%	4/6/2022	Smith
4/20/2022	Midazolam	Sterility	Pass	4/6/2022	Smith
3/21/2022	Potassium Chloride	Sterility	Pass	3/18/2022	Smith
3/31/2022	Potassium Chloride	Potency	103.00%	3/22/2022	Smith

1. Billy Ray Irick

In May 2018, the Pharmacy sent a sample of its first compounded batch of Midazolam to the external Lab for testing. That sample was tested for method suitability,⁷⁷ container closure integrity,⁷⁸ potency, bacterial endotoxins, and sterility.⁷⁹ Although not all tests are required under the USP, the Pharmacist explained that they requested these tests for their first compounded batch to ensure their compounding process was sound. The sample passed each of the tests and yielded a within-range potency of 97%. It appears that this lot was essentially a “test run,” given that this was the first time the Pharmacy would be compounding Midazolam rather than ordering it in commercially manufactured form. According to the Pharmacy Owner--in text messages⁸⁰ with the Drug Procurer--passing the method suitability test indicates that the Pharmacy’s method for compounding the drug is sound and translates across multiple batches. However, passing results on one batch for potency, sterility, and endotoxins does not necessarily indicate that a subsequent batch will yield the same test results. Based on the 45-day shelf life of compounded Midazolam, the batch tested in May 2018 would have surpassed its beyond-use date prior to Mr. Irick’s execution date in August 2018.

⁷⁷ Method suitability testing is performed to determine whether any inhibitory or antimicrobial properties in a drug product will prevent the sterility test from detecting the presence of viable microorganisms.

⁷⁸ Container closure integrity testing is performed to evaluate the adequacy of a closure in maintaining a sterile barrier.

⁷⁹ Testing Reports, attached hereto as Exhibit 41.

⁸⁰ Text messages between Drug Procurer and Pharmacy Owner, dated Aug. 8, 2019, attached hereto as Exhibit 42.

A physician's prescription for Midazolam was issued for Mr. Irick on July 18, 2018,⁸¹ and the Pharmacy compounded the Midazolam on July 20.⁸² A sample of that lot was sent for testing on or about July 21, 2018.⁸³ This lot was tested for sterility on August 6, 2018 and passed,⁸⁴ and the Pharmacy Owner sent those test results to the Drug Procurer via email the same day.⁸⁵ Text messages between the Drug Procurer and the Pharmacy Owner indicate that, at TDOC's urging, the Pharmacy Owner shipped the Midazolam to TDOC before receiving those test results.⁸⁶

This lot of Midazolam was not tested for potency or endotoxins. When the sterility test came back, the Drug Procurer asked the Pharmacy Owner via text message about the potency results.⁸⁷ The Pharmacy Owner replied that the pharmacist did not request a potency verification given that our methodology and suitability passed in May with the same midazolam lot.⁸⁸ The Drug Procurer asked whether this indicated that "the potency portion is good for that whole 50-gram batch."⁸⁹ The Pharmacy Owner responded:

"Our methodology is good for any batch of midazolam. It just verifies that how we process the compound yields the intended dosing within an acceptable range. Potency testing isn't required for every lot, however, given the sensitive nature of

⁸¹ Irick Prescription, dated July 18, 2018, attached hereto as Exhibit 43.

⁸² Email from Pharmacy Owner to Drug Procurer, dated Aug. 8, 2018, including copy of Logged Formula Worksheet, dated July 20, 2018, attached hereto as Exhibit 44.

⁸³ Testing Report, dated Aug. 6, 2018, attached hereto as Exhibit 45.

⁸⁴ *Id.* (25)

⁸⁵ Email from Pharmacy Owner to Drug Procurer, dated Aug. 6, 2018, including copy of Testing Report, dated Aug. 6, 2018, attached hereto as Exhibit 46.

⁸⁶ Text messages between Drug Procurer and Pharmacy Owner, dated July 25-26, 2018, attached hereto as Exhibit 47.

⁸⁷ Text messages between Drug Procurer and Pharmacy Owner, attached hereto as Exhibit 48.

⁸⁸ *Id.*

⁸⁹ Text messages between Drug Procurer and Pharmacy Owner, dated Aug. 7, 2018, attached hereto as Exhibit 49.

its intended use, I have instructed [the Pharmacist] to request it every time moving forward.”⁹⁰

The Drug Procurer accepted this explanation and did not inform the Pharmacy Owner that a potency test was nevertheless required under the Protocol. It appears that this batch of Midazolam was used in the execution of Mr. Irick on August 9, 2018.

2. Edmund Zagorski

Edmund Zagorski (“Mr. Zagorski”) was initially scheduled to be executed on October 11, 2018 by lethal injection.⁹¹ A physician’s prescription for Midazolam was issued for Mr. Zagorski on September 21, 2018.⁹² Upon compounding the Midazolam, the Pharmacy sent a sample of that lot to the Lab for testing on or about September 22, which was tested for both sterility and potency.⁹³ While this testing was pending, the Drug Procurer asked the Pharmacy Owner “to go ahead and ship the latest batch” on September 25, which the Pharmacy Owner did.⁹⁴ The sample ultimately passed the sterility test and yielded a within-range potency of 94.2%.⁹⁵ The Pharmacy Owner sent these results to the Drug Procurer via email on October 10, 2018.⁹⁶ The sample was not tested for endotoxins.

On October 8, Mr. Zagorski apparently submitted an Affidavit Concerning Method of Execution purporting to waive his right to execution by lethal injection and electing to be executed

⁹⁰ *Id.*

⁹¹ Zagorski Notification Letter, dated Sept. 27, 2018, attached hereto as Exhibit 30.

⁹² Zagorski Prescription, dated Sept. 21, 2018, attached hereto as Exhibit 51.

⁹³ Testing Reports, dated Sept. 24 and Oct. 8, 2018, attached hereto as Exhibit 52.

⁹⁴ Text messages between Drug Procurer and Pharmacy Owner, dated Sept. 25, 2018, attached hereto as Exhibit 53.

⁹⁵ Testing Reports, dated Sept. 24 and Oct. 8, 2018, attached hereto as Exhibit 54.

⁹⁶ Email from Pharmacy Owner to Drug Procurer, dated Oct. 10, 2018, including Testing Report, attached hereto as Exhibit 55.

by electrocution instead.⁹⁷ Given this late change, then Tennessee Governor Bill Haslam issued a reprieve on October 11, which remained in effect until October 21.⁹⁸ Mr. Zagorski ultimately confirmed his decision to be executed by electrocution, to which TDOC agreed, and his execution was rescheduled for November 1. Nevertheless, although not explicitly required by the Protocol, TDOC made the decision from that point forward to obtain LIC for each execution in the event of a last-minute method change. Accordingly, a second physician's prescription for Midazolam was issued for Mr. Zagorski on October 24,⁹⁹ the Pharmacy compounded the Midazolam, and sent a sample to the Lab for sterility and potency testing on or about October 27.¹⁰⁰ The sample was not tested for endotoxins. By the time the potency test was completed on November 7—yielding a below-range result of 54.2%—Mr. Zagorski had already been executed by electrocution on November 1.

3. David Earl Miller

David Earl Miller (“Mr. Miller”) was scheduled to be executed on December 6, 2018, and TDOC notified Mr. Miller by letter dated November 21 that it planned to carry out this execution by lethal injection.¹⁰¹ A physician's prescription for Midazolam was issued for Mr. Miller on November 16,¹⁰² and the Pharmacy compounded the Midazolam and sent a sample to the Lab for sterility and potency testing on or about November 21.¹⁰³ Mr. Miller elected to be executed by electrocution on November 23.¹⁰⁴ The sample later passed sterility testing but yielded a below-

⁹⁷ Letter from D. Inglis to K. Henry re: *State of Tennessee v. Edmund Zagorski*, M1996-00110-SC-DPE-DD, dated Oct. 9, 2018, attached hereto as Exhibit 56.

⁹⁸ Zagorski Reprieve, dated Oct. 11, 2018, attached hereto as Exhibit 57.

⁹⁹ Second Zagorski Prescription, attached hereto as Exhibit 58.

¹⁰⁰ Testing Report, dated Nov. 7, 2018, attached hereto as Exhibit 59.

¹⁰¹ Miller Notification Letter, dated Nov. 21, 2018, attached hereto as Exhibit 60.

¹⁰² Miller Prescription, dated Nov. 16, 2018, attached hereto as Exhibit 61.

¹⁰³ Testing Reports, dated Dec. 4, 5, 2018, attached hereto as Exhibit 62.

¹⁰⁴ Miller Notification Letter signed by Miller, dated Nov. 23, 2018, attached hereto as Exhibit 63.

range potency of 89.4%.¹⁰⁵ The sample was not tested for endotoxins. The Midazolam was not used, as Mr. Miller was executed by electrocution on December 6 as scheduled.

4. Donnie Edward Johnson

Donnie Edward Johnson ("Mr. Johnson") was scheduled to be executed on May 16, 2019 by lethal injection.¹⁰⁶ A physician's prescription for Midazolam was issued for Mr. Johnson on April 17, 2019,¹⁰⁷ the Pharmacy compounded the Midazolam, and sent a sample to the Lab for sterility and potency testing on or about April 25.¹⁰⁸ The potency test came back first, on April 26, with a within-range result of 104%. The Pharmacy Owner sent this result to the Drug Procurer on April 29.¹⁰⁹ While the sterility test was still pending, the Drug Procurer asked the Pharmacy Owner via text message if they could send the Midazolam to TDOC early, stating "[It would] be good to go ahead and get it stored since next week will be execution week and a little hectic."¹¹⁰ The Pharmacy Owner agreed and shipped the Midazolam on May 8 via priority overnight.¹¹¹ The package arrived and the sterility test came back the next day--May 9--with a passing result, which the Pharmacy Owner sent to the Drug Procurer.¹¹² The sample was not tested for endotoxins. Mr. Johnson was executed by lethal injection on May 16 as scheduled with the compounded Midazolam received from the Pharmacy and the unexpired, commercially-manufactured

¹⁰⁵ Testing Reports, Exhibit 64.

¹⁰⁶ Johnson Notification Letter, dated Apr. 16, 2019, attached hereto as Exhibit 65.

¹⁰⁷ Johnson Prescription, dated Apr. 17, 2019, attached hereto as Exhibit 66.

¹⁰⁸ Testing Reports, dated Apr. 26 and May 9, 2019, attached hereto as Exhibit 67.

¹⁰⁹ Email from Pharmacy Owner to Drug Procurer, dated Apr. 29, 2019, including Testing Report, attached hereto as Exhibit 68.

¹¹⁰ Text messages between Pharmacy Owner and Drug Procurer, dated May 8, 2019, attached hereto as Exhibit 69.

¹¹¹ Text messages between Pharmacy Owner and Drug Procurer, dated May 8, 2019, attached hereto as Exhibit 70.

¹¹² Text messages between Pharmacy Owner and Drug Procurer, dated May 9, 2019, attached hereto as Exhibit 71; Email from Pharmacy Owner to Drug Procurer, dated May 9, 2019, including Testing Report, attached hereto as Exhibit 72.

Vecuronium Bromide and Potassium Chloride that TDOC still had in its inventory. Following Mr. Johnson's execution, on May 20, 2019, Ms. Henry requested "all data regarding the lethal injection chemicals used in the execution including the results of the sterility testing of the chemicals[.]"¹¹³

5. Stephen West

Stephen West ("Mr. West") was scheduled to be executed on August 15, 2019 by lethal injection.¹¹⁴ Because the Potassium Chloride in TDOC's inventory would expire in July 2019, TDOC needed to acquire both Midazolam and Potassium Chloride in advance of Mr. West's planned execution. As with the Midazolam in early 2018, the Pharmacy was no longer able to obtain commercially-manufactured Potassium Chloride, necessitating it to compound the drug instead. In preparation for this switch, the Pharmacist drafted separate Preparation Instructions for Potassium Chloride at the Drug Procurer's request.¹¹⁵ The Pharmacy Owner and Drug Procurer exchanged drafts of these instructions on June 26, 2019, with the Drug Procurer making edits to the quantity of saline, number of syringes, and certain outlined steps.¹¹⁶ The Pharmacy Owner forwarded the Drug Procurer's revised draft to the Pharmacist, who approved the same on July 2.¹¹⁷ Like the Midazolam Preparation Instructions, these instructions require transfer of the compounded Potassium Chloride from the freezer to the refrigerator 24 hours prior to use and explain how to prepare the syringe, but they do not instruct on how far in advance of an execution to prepare that syringe.

¹¹³ Email from K. Henry to D. Inglis, dated May 20, 2019, attached hereto as Exhibit 73.

¹¹⁴ West Notification Letter, attached hereto as Exhibit 74.

¹¹⁵ Text messages between Drug Procurer and Pharmacy Owner, dated June 17, 21 and 24, 2019, attached hereto as Exhibit 75.

¹¹⁶ Emails between Drug Procurer and Pharmacy Owner, dated June 26, 2019, including Potassium Chloride Preparation Instructions, attached hereto as Exhibit 76.

¹¹⁷ Emails between Drug Procurer, Pharmacy Owner and Pharmacist, dated June 26 and July 2, 2019, attached hereto as Exhibit 77.

A physician's prescription for Midazolam and Potassium Chloride was issued for Mr. West on July 12, 2019.¹¹⁸ The Pharmacy compounded the Midazolam and Potassium Chloride and sent samples to the Lab for sterility and potency testing on or about July 16.¹¹⁹

The Midazolam sample yielded a within-range potency of 92.4% on July 18, but the Potassium Chloride sample yielded an above-range potency of 112% on July 17.¹²⁰ The Pharmacy Owner sent both results to the Drug Procurer on July 24.¹²¹ By separate text message, the Pharmacy Owner instructed the Drug Procurer to "scratch that batch" of Potassium Chloride in light of the above-range potency result and informed the Drug Procurer that the Pharmacy had prepared and sent another batch for testing.¹²² The Midazolam sample passed sterility testing on July 30, and the Pharmacy Owner sent those results to the Drug Procurer via email the next day.¹²³

On August 1, the Pharmacy Owner informed the Drug Procurer via text message that the Pharmacy was "having issues with the potassium chloride" and that they "can't use it" because it was "falling out of solution."¹²⁴ According to investigative interviews, when a drug is falling out of solution, it means the API is not fully dissolving into the intended liquid form during the compounding process. The Pharmacy ultimately compounded several batches and sent a successful sample of one of those batches to the Lab for sterility and potency testing on or about

¹¹⁸ West Prescription, dated July 12, 2019, attached hereto as Exhibit 78.

¹¹⁹ Testing Reports, dated July 17, 30, 2019, attached hereto as Exhibit 79.

¹²⁰ *Id.*

¹²¹ Email from Pharmacy Owner to Drug Procurer, dated July 24, 2019, including Testing Reports, attached hereto as Exhibit 80.

¹²² Text messages between Pharmacy Owner and Drug Procurer, dated July 29-31, 2019, attached hereto as Exhibit 81.

¹²³ Email from Pharmacy Owner to Drug Procurer, dated July 31, 2019, including Testing Report, attached hereto as Exhibit 82.

¹²⁴ Text messages between Pharmacy Owner and Drug Procurer, dated Aug. 1, 2019, attached hereto as Exhibit 83.

August 6, 2019.¹²⁵ It appears a separate sample was also sent for Suitability testing and passed.¹²⁶ On August 8, while this testing was pending, the Drug Procurer asked the Pharmacy Owner via text message if they could send the LIC the following day, explaining “[the] higher ups [don’t] wanna [sic] wait till [sic] Tuesday.”¹²⁷ The Pharmacy Owner agreed. The Drug Procurer also asked if they could rely on the sterility testing from a prior batch of Potassium Chloride for sterility on the new batch.¹²⁸ Initially, the Pharmacy Owner replied “Absolutely.” However, in response to further questioning by the Drug Procurer regarding USP guidelines for relying on testing from a prior batch, the Pharmacy Owner explained “You could rely on that as proof that our methodology is valid. You cannot apply one lot’s sterility to another lot.”¹²⁹

The Drug Procurer and Pharmacy Owner made further edits to the Pharmacy’s instructions for Potassium Chloride on August 8.¹³⁰ On August 9, the Pharmacy Owner also sent the Drug Procurer an “in-house sterility report” for the Potassium Chloride batch, which showed a passing result.¹³¹ The Drug Procurer continued to follow up with the Pharmacy Owner via text message in the subsequent days regarding test results.¹³² On August 12, the Pharmacy Owner emailed the potency test report for the Potassium Chloride, which showed a within-range potency of 94%.¹³³

¹²⁵ Testing Reports, dated Aug. 7, 12, 2019, attached hereto as Exhibit 84.

¹²⁶ Testing Reports, dated July 31, 2019, attached hereto as Exhibit 85.

¹²⁷ Text messages between Drug Procurer and Pharmacy Owner, dated Aug. 8, 2019, attached hereto as Exhibit 86.

¹²⁸ Text messages between Drug Procurer and Pharmacy Owner, attached hereto as Exhibit 87.

¹²⁹ Text messages between Drug Procurer and Pharmacy Owner, dated Aug. 8, 2019, attached hereto as Exhibit 88.

¹³⁰ Emails between Drug Procurer and Pharmacy Owner, dated Aug. 8, 2019, including Potassium Chloride Preparation Instructions, attached hereto as Exhibit 89.

¹³¹ Email from Pharmacy Owner to Drug Procurer, dated Aug. 9, 2019, including In-House Sterility Report, dated Aug. 6, 2019, attached hereto as Exhibit 90. Note that the Protocol requires the Pharmacist to arrange independent testing of the LIC. See Protocol, Exhibit 20 at 35.

¹³² Text messages between Drug Procurer and Pharmacy Owner, dated Aug. 8-12, 2019, attached hereto as Exhibit 91.

¹³³ Emails from Pharmacy Owner to Drug Procurer, dated Aug. 12, 2019, including Testing Reports dated Aug. 7, 12, 2019, attached hereto as Exhibit 92.

The sample was not tested for endotoxins. Ultimately, Mr. West elected to be executed by electrocution, which proceeded as scheduled on August 15.

6. Lee Hall

Lee Hall ("Mr. Hall") was scheduled to be executed on December 5, 2019 by lethal injection.¹³⁴ A physician's prescription for Midazolam and Potassium Chloride was issued for Mr. Hall on November 1, 2019.¹³⁵ Shortly thereafter, Mr. Hall elected to be executed by electrocution; however, consistent with its practice, TDOC proceeded to obtain back-up LIC. The Pharmacy compounded a batch of Midazolam and sent a sample to the Lab for sterility and potency testing on or about November 13.¹³⁶ The potency test came back on November 18 with an above-range potency of 114%. The Pharmacy Owner sent this result to the Drug Procurer via email on November 20.¹³⁷

The Pharmacy compounded a second batch of Midazolam and sent a sample to the Lab for sterility and potency testing on or about November 21.¹³⁸ The potency test on that sample came back on November 22 with a within-range potency of 98.6%. On November 25, the Pharmacy Owner shipped two packages to the Drug Procurer—presumably the Midazolam and Potassium Chloride—and sent shipping information via text message.¹³⁹ The Pharmacy Owner then sent the Midazolam potency result to the Drug Procurer via email on November 26.¹⁴⁰

¹³⁴ Hall Notification Letter, dated Nov. 5, 2019, attached hereto as Exhibit 93.

¹³⁵ Hall Prescription, dated Nov. 1, 2019, attached hereto as Exhibit 94.

¹³⁶ Testing Reports, dated Nov. 18, 2019, attached hereto as Exhibit 95.

¹³⁷ Email from Pharmacy Owner to Drug Procurer, dated Nov. 20, 2019, including Testing Report dated Nov. 18, 2019, attached hereto as Exhibit 96.

¹³⁸ Testing Report, dated Nov. 22, 2019, attached hereto as Exhibit 97.

¹³⁹ Text messages between Drug Procurer and Pharmacy Owner, dated Nov. 25, 2019, attached hereto as Exhibit 98.

¹⁴⁰ Email from Pharmacy Owner to Drug Procurer, dated Nov. 26, 2019, attached hereto as Exhibit 99.

At some point, the Pharmacy also compounded a batch of Potassium Chloride and sent it to the Lab for sterility and potency testing; however, on December 2, the Pharmacy Owner texted the Drug Procurer to inform him that they had “missed the mark by 2% points” on the Potassium Chloride and were sending a new batch.¹⁴¹ The Pharmacy sent a sample of that new batch to the Lab for potency and sterility testing on or about December 2.¹⁴² The Pharmacy Owner then mailed the new Potassium Chloride to TDOC on December 3.¹⁴³ On December 5, the second batch of Midazolam passed sterility testing and the second batch of Potassium Chloride yielded a within-range potency of 94.7%.¹⁴⁴ The Pharmacy Owner sent both results to the Drug Procurer the same day.¹⁴⁵ Mr. Hall was executed via electrocution as scheduled that evening. The Pharmacy did not receive a passing sterility result on the Potassium Chloride until December 16.¹⁴⁶ None of the samples were tested for endotoxins.

7. Nicholas Sutton

Nicholas Sutton (“Mr. Sutton”) was scheduled to be executed on February 20, 2020. A physician’s prescription for Midazolam and Potassium Chloride was issued for Mr. Sutton on December 19, 2019.¹⁴⁷ Around that time, the Pharmacy Owner—TDOC’s only contact at the Pharmacy—began transitioning out of the Pharmacy as a result of a buyout of their ownership share, with their last day scheduled for January 15, 2020.¹⁴⁸ The Drug Procurer and the New

¹⁴¹ Text messages between Drug Procurer and Pharmacy Owner, dated Nov. 25 and Dec. 2, 2019, attached hereto as Exhibit 100.

¹⁴² Testing Reports, dated Dec. 5, 16, 2019, attached hereto as Exhibit 101.

¹⁴³ Text messages between Drug Procurer and Pharmacy Owner, dated Dec. 3, 2019, attached hereto as Exhibit 102.

¹⁴⁴ Testing Reports, dated Nov. 22, Dec. 5, 16, 2019, attached hereto as Exhibit 103.

¹⁴⁵ Email from Pharmacy Owner to Drug Procurer, dated Dec. 5, 2019, including Testing Reports dated Nov. 22 and Dec. 5, 2019, attached hereto as Exhibit 104.

¹⁴⁶ Testing Reports, dated Dec. 5, 16, 2019, attached hereto as Exhibit 105.

¹⁴⁷ Sutton Prescription, dated Dec. 19, 2019, attached hereto as Exhibit 106.

¹⁴⁸ Text messages between Drug Procurer and Pharmacy Owner, dated Dec. 25, 2019 and Jan. 2, 2020, attached hereto as Exhibit 107.

Pharmacy Owner discussed TDOC's desire to continue working with the Pharmacy. Thereafter, the Drug Procurer began communicating directly with the Pharmacist, not the Pharmacy Owner.

The Pharmacy compounded the Midazolam and Potassium Chloride and sent samples to the Lab for sterility and potency testing on or about January 14, 2020.¹⁴⁹ The Potassium Chloride yielded a within-range potency of 104% on January 17.¹⁵⁰ On January 21, Mr. Sutton elected to be executed by electrocution.¹⁵¹ The Midazolam ultimately yielded a within-range potency of 100% on January 27, and both the Midazolam and Potassium Chloride passed their sterility tests on January 28.¹⁵² The samples were not tested for endotoxins. Butler Snow has not seen any record to indicate that the Pharmacist sent these results to TDOC prior to Mr. Sutton's execution. Mr. Sutton was executed by electrocution as scheduled on February 20, 2020.

C. Clarity of and Adherence to the July 2018 Protocol

1. Inconsistencies in the Protocol

Many individuals interviewed by Butler Snow indicated that there are inconsistencies contained with the July 2018 Protocol. The interviewees attributed any inconsistencies to revisions being made to one section or an addition of a new section without reviewing the entire document to determine if other areas have been impacted. Beyond the LIC testing failures that are the primary focus of this investigation, gaps and inconsistencies have been noted, particularly by TDOC employees, but changes have yet to be made. For instance, as noted above, one of the most significant gaps is the absence of any reference to the Drug Procurer or their responsibilities in the Protocol. It is Butler Snow's understanding that although the term "Drug Procurer" came about through litigation, the Drug Procurer responsibilities preexisted any litigation referencing the role. The current Protocol does not have any discussion of steps to be taken by the Drug Procurer when

¹⁴⁹ Testing Reports, dated Jan. 17, 27, 28, 2020, attached hereto as Exhibit 108.

¹⁵⁰ Testing Reports, dated Jan. 17, 28, 2020, attached hereto as Exhibit 109.

¹⁵¹ Sutton Affidavit Concerning Method of Execution, attached hereto as Exhibit 110.

¹⁵² Testing Reports, dated Jan. 17, 27, 28, 2020, attached hereto as Exhibit 111.

acquiring LIC. Furthermore, there is no discussion of how the Drug Procurer (or any other individual) should go about confirming that the required independent testing has been conducted.

Another issue with the current Protocol raised during the investigative interviews addressed the storage and accountability of the compounded LIC. For example, the Protocol states that the compounded LIC are to be stored in “an unmovable heavy gauge steel container with security grade locks.”¹⁵³ The Investigative Team observed that the LIC are stored securely but not in an “unmovable heavy gauge steel container” as mandated. As a result, the Protocol should be revised to reflect the true nature in which the LIC are stored. There are also no LIC temperature requirements referenced in the Protocol, no LIC storage guidelines, or instructions regarding when the LIC should be removed to allow for thawing. Accordingly, TDOC relies exclusively on the instructions from the Pharmacy with regard to how the compounded LIC are to be stored.¹⁵⁴

Finally, another unanswered question exists regarding how far in advance of an execution a compounded LIC should be removed from the refrigerator and prepared in a syringe. Neither the Protocol nor the Pharmacy’s instructions address this issue. The compounded LIC have a very short shelf-life, and this information is seemingly essential to ensuring an execution is carried out with only viable LIC.

2. Following the Protocol

Inconsistencies in the Protocol preclude TDOC’s ability to follow the Protocol to the letter in practice, and there is no formal process for determining if and when TDOC should deviate from the Protocol. The most egregious deviation seen by Butler Snow is the failure to test the LIC for endotoxins (and potency in Mr. Irick’s case). The Drug Procurer indicated that they consulted the Pharmacy Owner when drafting the July 2018 Protocol. The similarities in language used in the revised January 2018 Protocol and the Pharmacy Services Agreement relating to same corroborate the Drug Procurer’s recollection; however, Butler Snow has not uncovered any written

¹⁵³ July 2018 Protocol, Exhibit 20 at 35.

¹⁵⁴ Directions for Unpacking and Storage, Exhibit 23.

communications between the Drug Procurer and the Pharmacy Owner regarding changes to the Protocol between January and July 2018. Similarly, Butler Snow has found no evidence that the current Protocol was ever sent to the Pharmacy. Instead, it appears that the Drug Procurer only sent the six-page drafts of sections regarding the chemicals used, their set-up and preparation, and the sequence and administration of the chemicals during the process of preparing the initial January 2018 iteration of the Protocol.

Both the Pharmacy Owner and Drug Procurer shared a misunderstanding of endotoxin testing, specifically whether such testing is included in sterility testing, and based on this misunderstanding, it appears neither consulted the Pharmacist on this topic in the course of discussing the July 2018 Protocol. Crucially, the Pharmacy never received a copy of these revisions or a complete copy of the July 2018 Protocol from TDOC, and the Pharmacist was never informed that the Protocol requires testing for potency, sterility, and endotoxins.

Other examples include the storage of the LIC, as well as TDOC's efforts to have LIC on hand even if the condemned has chosen electrocution as the method of execution. This practice began after the execution of Mr. Zagorski, but at least one TDOC employee indicated that the decision to have LIC on hand as a backup method is not required by the Protocol. Another example is in the disposal of expired LIC. Under the Protocol, the LIC is to be *disposed of upon expiration by hazardous waste pick-up*. However, inspections are only required to be done on a semi-annual basis, and on at least one occasion, LIC were disposed of that had been expired for several months.¹⁵⁵ With only semi-annual inspections, it is possible that expired LIC may be sitting for months before being disposed of in accordance with the Protocol, which increases the possibility of expired LIC being used inadvertently during an execution.

At least one TDOC employee indicated that when reviewed by a person familiar with the actual process followed during an execution, the Protocol is not strictly followed because it is inaccurate. Timing of events during execution was specifically noted as an area of the Protocol that needed to be examined and revised.

¹⁵⁵ Dep. Tr. of Warden Tony Mays at 193:25-196:25, attached hereto as Exhibit 112.

3. No Checks and Balances

There are no internal policies to ensure the Protocol is followed. Deviations occur, and although such deviations may ensure compliance with USP guidelines in the context of compounded LIC, this does not change the fact that the Protocol is not being followed. Commissioners Parker and Helton both indicated that it is ultimately their responsibility to ensure the Protocol is being followed, but to do so, a more rigorous review system must be put in place to ensure accountability. Several individuals referenced TDOC's general preference to have limited documentation and a hesitance to make changes to the Protocol, but the overall sense is that the Protocol needs to be reviewed to ensure that it is consistent in all aspects.

Furthermore, there is no structured review process. Members of the Execution Team¹⁵⁶ are required to review the Protocol annually once they become members of the Execution Team, but there is no verification process. According to the Protocol, the Warden or his designee holds an annual class to review the Protocol, but this training was not mentioned during Butler Snow's interviews with TDOC employees. Some RMSI training records identify the topic of training as "Protocol" via "lethal injection" or "electrocution," which may be a reference to the above-referenced class. When asked, some individuals stated they review the entire Protocol multiple times a year, and many indicated that they review portions of the Protocol when needed. It is imperative that all individuals involved understand what is required under the Protocol and how to meet those requirements. See recommendations below for how to improve this process.

¹⁵⁶ Under the Protocol, the Execution Team consists of the Warden, Associate Warden of Security, Executioner, IV Team, Extraction Team, Death Watch Team, Lethal Injection Recorder, Facility Maintenance Supervisor, ITS Security Systems Technician(s), and Escort Officers. July 2018 Protocol at 32.

D. TDOC Staffing Considerations

Butler Snow also attended one of the monthly lethal injection training sessions to observe the TDOC staff's involvement in the execution process. This allowed the investigative team to assess (1) the staff's expertise in carrying out lethal injection executions and (2) their ability to comply with the current Protocol. Butler Snow notes that all TDOC training participants appeared to be extremely professional, serious, dedicated and committed.

As far as the failure to test the LIC for endotoxins, there were no checks and balances in place to ensure testing occurred. Butler Snow's investigation revealed that neither the Pharmacy nor the Pharmacist ever received a full copy of the July 2018 Protocol, or even a partial copy that spoke to the testing requirements. Only one TDOC employee—the Drug Procurer—received the testing reports from the Pharmacy, and as a result, no one else had any insight into whether the LIC were prepared and tested in accordance with the Protocol. It should be noted that the Drug Procurer does not have a medical or pharmaceutical background, and as a result, they do not have any formal training that would aid them in understanding testing reports or assessing which tests are necessary for compounded LIC. It should be further noted that there is no Drug Procurer job description or list of duties stating that they are responsible for ensuring the LIC are properly tested in accordance with the current Protocol. Even so, a plain reading of the third-party lab reports indicates that only one endotoxin test occurred, and that was in May 2018. The fact of the matter is not one TDOC employee made it their duty to understand the current Protocol's testing requirements and ensure compliance with same. And, based upon information provided during investigative interviews, the Former Commissioner; Interim Commissioner; Deputy Commissioner/General Counsel; and Drug Procurer were in the best positions to ensure compliance with the Protocol.

While medical training may not be strictly necessary to perform the roles required for executions, it is certainly beneficial. Members of the Execution Team receive some medical training on how to start IVs, but other instruction on preparing and delivering the LIC during an execution came via instructions and a phone call with the Pharmacy. The Pharmacy Owner recalled that their impression from that phone call was that the members of the Execution Team they spoke

with were inexperienced in preparing syringes for injection. Neither the Executioner nor the IV Team Member recalled this phone call at the time of this Investigation. Even though the Executioner¹⁵⁷ has no formal healthcare training, they have participated in 13 executions for the state of Tennessee and have observed an execution in at least 1 other state. They learned how to fulfill their role primarily through on-the-job training and are very experienced at this point in time. It would be difficult to find another individual, however, with this experience and/or medical training to perform executions, because of the Hippocratic oath. Accordingly, in the event that this individual leaves TDOC, there does not appear to be anyone in place prepared or qualified to assume this role.

Additionally, placing the onus of finding LIC and verifying that the LIC are fit for use per the Protocol and USP guidelines is an enormous task to place on one individual, especially when they have other roles to fill and particularly when they are given zero guidance on how to carry out these tasks. Moreover, this method does not allow for any checks and balances whatsoever. Putting all of this responsibility on one person seems like an abdication of responsibility by TDOC leadership and the reason for the failures to comply with the current Protocol cited in this Report. See the recommendations below for how to remedy this issue.

IV. Investigative Findings and Recommendations

As independent investigators, Butler Snow conducted a comprehensive review of the available and relevant evidence concerning the circumstances which led Governor Lee to issue a reprieve in connection with the April 21, 2022, scheduled execution of Mr. Smith. In addition to this issue, the investigative team also (1) examined Tennessee's Lethal Injection Protocol and any deviations from same prior to April 21 and (2) determined the extent of TDOC's staff's responsibility relating to these issues. As previously stated, the investigative findings are primarily based upon the information gleaned through witness interviews as well as an extensive review of thousands of pages of documents and/or data. While the interviews were very insightful, they

¹⁵⁷ The Executioner is not involved in the testing of the LIC but is aware of the requirement by virtue of the Protocol.

further showed the absence of adequate expertise, guidance, and counsel either enlisted by or provided to TDOC in connection with Tennessee's lethal injection process. Instead, TDOC operated in a task-oriented, tunnel-vision manner that failed to appreciate the interwoven nature of the lethal injection process as a whole.

A. Investigative Findings

Based on the evidence obtained in the investigation, Butler Snow has made the following findings:

- 1. Circumstances that led to testing the lethal injection chemicals for only potency and sterility but not endotoxins [in connection with] preparing for the April 21 execution**
 - There is no evidence that any failure to test the lethal injection chemicals for endotoxins in connection with Mr. Smith's scheduled execution on April 21 was intentional.
 - There is no evidence that, when the State of Tennessee revised its lethal injection protocol in 2018, it ever provided the pharmacy tasked with testing Tennessee's lethal injection chemicals with a copy of Tennessee's lethal injection protocol.
 - There is no evidence that, when the State of Tennessee revised its lethal injection protocol in 2018, any employee ever informed the pharmacy tasked with testing Tennessee's lethal injection chemicals that it should conduct an endotoxin test on all lethal injection chemicals—until the eve of Mr. Smith's scheduled execution on April 21.
 - The evidence shows that the pharmacy tasked with testing Tennessee's lethal injection chemicals only tested these chemicals for *potency and sterility*, because the pharmacy followed the United States Pharmacopeia testing guidelines, not Tennessee's lethal injection protocol.
- 2. Clarity of the lethal injection process manual that was last updated in 2018, and adherence to testing policies since the update**
 - The evidence shows that the lethal injection chemicals used in the August 9, 2018, execution of Mr. Billy Ray Irick ("Mr. Irick") were not tested for endotoxins. The evidence further shows that the Midazolam used during Mr. Irick's execution was not tested for potency.
 - The evidence shows that, although Edmund Zagorski ("Mr. Zagorski") was executed via electrocution on November 1, 2018, the lethal injection chemicals prepared in the event

Mr. Zagorski changed his mind and opted to be executed by lethal injection were not tested in accordance with Tennessee's lethal injection protocol. The lethal injection chemicals were not tested for endotoxins and failed the potency testing.

- The evidence shows that, although David Earl Miller ("Mr. Miller") was executed via electrocution on December 6, 2018, the lethal injection chemicals prepared in the event Mr. Miller changed his mind and opted to be executed by lethal injection were not tested in accordance with Tennessee's lethal injection protocol. The lethal injection chemicals were not tested for endotoxins.
- The evidence shows that the lethal injection chemicals used in the May 16, 2019, execution of Mr. Donnie Edward Johnson ("Mr. Johnson") were not tested for endotoxins.
- The evidence shows that, although Stephen West ("Mr. West") was executed via electrocution on August 15, 2019, the lethal injection chemicals prepared in the event Mr. West changed his mind and opted to be executed by lethal injection were not tested in accordance with Tennessee's lethal injection protocol. The lethal injection chemicals were not tested for endotoxins.
- The evidence shows that, although Lee Hall ("Mr. Hall") was executed via electrocution on December 5, 2019, the lethal injection chemicals prepared in the event Mr. Hall changed his mind and opted to be executed by lethal injection were not tested in accordance with Tennessee's lethal injection protocol. The lethal injection chemicals were not tested for endotoxins.
- The evidence shows that, although Nicholas Sutton ("Mr. Sutton") was executed via electrocution on February 20, 2020, the lethal injection chemicals prepared in the event Mr. Sutton changed his mind and opted to be executed by lethal injection were not tested in accordance with Tennessee's lethal injection protocol. The lethal injection chemicals were not tested for endotoxins.

3. TDOC staffing considerations

- The evidence shows that TDOC leadership placed an inordinate amount of responsibility on the Drug Procurer without providing much, if any, guidance; help; or assistance. Instead, TDOC leadership viewed the lethal injection process through a tunnel-vision, result-oriented lens rather than provide the necessary guidance and counsel to ensure that Tennessee's lethal injection protocol was thorough, consistent, and followed.

B. Recommendations

The instant investigation has helped bring to light issues that have impacted TDOC's ability to comply with Tennessee's Lethal Injection Protocol since it was put in place in 2018. As a result,

Butler Snow makes the following recommendations for corrective action, further investigation, or training:

- Consider hiring a full-time employee or retaining a consultant with a pharmaceutical background to provide guidance in connection with the lethal injection process.
 - Conduct an exhaustive review of the current Protocol.
 - Review the current Protocol's testing requirements.
 - Establish testing guidelines for any compounded LIC with procedures for confirming that the appropriate tests are being performed.
 - Establish a procedure for storing and maintaining test results.
 - Establish a procedure for storing and maintaining LIC, including recommendations regarding suitable equipment for storage.
 - Assist with locating LIC sources and communicating pertinent information to same.
- Ensure that a copy of any current or future version of the TDOC Protocol is provided to the LIC provider.
- Evaluate the roles and outline the duties of all TDOC employees, as well as any third parties, tasked with participating in the lethal injection process.
- Consider hiring a full-time employee or retaining a consultant with a healthcare background to provide scheduled guidance and training to the Execution Team.
 - Determine whether any Execution Team members should be required to obtain any certifications and/or licenses.
- Establish a team/committee to review all relevant testing data prior to each scheduled execution to ensure that there are no deviations from the Protocol.
 - Consider incorporating deadlines to obtain testing results in sufficient time to ensure that failing LIC are not made available or used during a scheduled execution.
 - Consider annual audits to ensure compliance and to evaluate Protocol efficiencies and best practices.